

I. AMENDMENTS AND LISTING OF CLAIMS

A. Amendments to the Claims

This listing of claims will replace all prior versions and listings of claims in the application. Applicant respectfully requests that these amendments be entered, as they are intended to reduce the number of issues on appeal.

B. Listing of Claims

1 (Currently Amended): A method for alleviating or reducing ~~the toxic, nutritional and metabolic disturbances associated with cancer and~~ fatigue and weakness in a patient undergoing cancer chemotherapy comprising: administering to a patient undergoing cancer chemotherapy a composition consisting of an effective amount of riboflavin[[],]; an effector of the urea cycle selected from the group consisting of arginine, ornithine citrulline, and mixtures thereof[[],]; and the amino acids alanine, glycine, serine, taurine, threonine and valine[[],]; and a suitable solvent, diluent, excipient or carrier.

2 (Cancelled)

3 (Original): The method of claim 1 wherein the amino acids are in free form or pharmacologically acceptable salts.

4 (Original): The method of claim 1, wherein the concentration of riboflavin is about 5 to about 300 mg/L.

5 (Original): The method of claim 1, wherein the concentration of the effector of the urea cycle is about 2 to about 120 mg/L.

6 (Original): The method of claim 1, wherein the concentration of alanine is about 1 to about 90 mg/L, the concentration of glycine is about 1 to about 75 mg/L, the concentration of serine is

about 1 to about 75 mg/L, the concentration of taurine is about 0.5 to about 30 mg/L, the concentration of threonine is about 1 to about 90 mg/L and the concentration of valine is about 1 to about 50 mg/L.

7 (Original): The method of claim 1, wherein said composition is administered enterally or parenterally.

8 (Original): The method of claim 1, wherein composition is administered intravenously.

9 (Cancelled)

10 (Currently Amended) The method of claim 1, wherein the composition consists of riboflavin, arginine, alanine, glycine, serine, taurine, threonine, valine and a pharmaceutically-acceptable solvent, carrier, excipient, or diluent.

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11 (Original): The method of claim 10, wherein the concentration of riboflavin is about 5 to about 300 mg/L, the concentration of arginine is about 2 to about 120 mg/L, the concentration of alanine is about 1 to about 90 mg/L, the concentration of glycine is about 1 to about 75 mg/L, the concentration of serine is about 1 to about 75 mg/L, the concentration of taurine is about 0.5 to about 30 mg/L, the concentration of threonine is about 1 to about 90 mg/L and the concentration of valine is about 1 to about 50 mg/L.

12 (Currently Amended) The method of claim 1, wherein the composition consists of riboflavin, ornithine, alanine, glycine, serine, taurine, threonine, valine and a pharmaceutically-acceptable solvent, carrier, excipient, or diluent.

13 (Original): The method of claim 12, wherein the concentration of riboflavin is about 5 to about 300 mg/L, the concentration of ornithine is about 2 to about 120 mg/L, the concentration of alanine is about 1 to about 90 mg/L, the concentration of glycine is about 1 to about 75 mg/L, the concentration of serine is about 1 to about 75 mg/L, the concentration of taurine is about 0.5

to about 30 mg/L, the concentration of threonine is about 1 to about 90 mg/L and the concentration of valine is about 1 to about 50 mg/L.

14 (Currently Amended) A pharmaceutical composition for alleviating or reducing ~~the toxic, nutritional and metabolic disturbances~~ fatigue and weakness associated with cancer and cancer chemotherapy consisting of: an effective amount of riboflavin[.,,]; an effector of the urea cycle selected from the group consisting of arginine, ornithine or citrulline and mixtures thereof[.,,]; ~~and~~ the amino acids alanine, glycine, serine, taurine, threonine, and valine[.,,]; and a suitable solvent, diluent, excipient, or carrier.

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15 (Currently Amended) The pharmaceutical composition of claim 14, wherein the effector of the urea cycle is ~~selected from arginine, ornithine or citrulline, wherein the effector is in free form or a pharmacologically acceptable salt.~~

16 (Original): The pharmaceutical composition of claim 14 wherein the amino acids are in free form or pharmacologically acceptable salts.

17 (Original): The pharmaceutical composition of claim 14, wherein the concentration of riboflavin is about 5 to about 300 mg/L.

18 (Original): The pharmaceutical composition of claim 14, wherein the concentration of the effector of the urea cycle is about 2 to about 120 mg/L.

19 (Original): The pharmaceutical composition of claim 14, wherein the concentration of alanine is about 1 to about 90 mg/L, the concentration of glycine is about 1 to about 75 mg/L, the concentration of serine is about 1 to about 75 mg/L, the concentration of taurine is about 0.5 to about 30 mg/L, the concentration of threonine is about 1 to about 90 mg/L and the concentration of valine is about 1 to about 50 mg/L.

20 (Original): The pharmaceutical composition of claim 14, having a pH of about 6.0 to about 7.0.

21 (Cancelled)

22 (Original): The pharmaceutical composition of claim 14, consisting of riboflavin, arginine, alanine, glycine, serine, taurine, threonine, valine and a pharmaceutically-acceptable carrier or diluent.

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23 (Original): The pharmaceutical composition of claim 22, wherein the concentration of riboflavin is about 5 to about 300 mg/L, the concentration of arginine is about 2 to about 120 mg/L, the concentration of alanine is about 1 to about 90 mg/L, the concentration of glycine is about 1 to about 75 mg/L, the concentration of serine is about 1 to about 75 mg/L, the concentration of taurine is about 0.5 to about 30 mg/L, the concentration of threonine is about 1 to about 90 mg/L and the concentration of valine is about 1 to about 50 mg/L.

24 (Currently Amended) The pharmaceutical composition of claim 14, consisting of riboflavin, ornithine, alanine, glycine, serine, taurine, threonine, valine and a pharmaceutically-acceptable solvent, carrier, excipient, or diluent.

25 (Original): The pharmaceutical composition of claim 24, wherein the concentration of riboflavin is about 5 to about 300 mg/L, the concentration of ornithine is about 2 to about 120 mg/L, the concentration of alanine is about 1 to about 90 mg/L, the concentration of glycine is about 1 to about 75 mg/L, the concentration of serine is about 1 to about 75 mg/L, the concentration of taurine is about 0.5 to about 30 mg/L, the concentration of threonine is about 1 to about 90 mg/L and the concentration of valine is about 1 to about 50 mg/L.

26 (Currently Amended): A method for alleviating or reducing ~~the toxic, nutritional and metabolic disturbances associated with cancer and~~ fatigue and weakness in a patient undergoing cancer chemotherapy comprising: administering to a patient undergoing cancer chemotherapy a

composition consisting of an effective amount of riboflavin; an effector of the urea cycle ~~comprising~~ consisting of arginine, ~~and~~ ornithine, and mixtures thereof; ~~and~~ the amino acids alanine, glycine, serine, threonine and valine; ~~and~~ a suitable solvent, diluent, excipient, or carrier; and ~~optionally~~ 3-phenylacetyl-amino-2,6-piperidinedione.

27 (Cancelled)

28 (Original): The method of claim 26, wherein the composition consists of 0.01-10 wt % riboflavin, 1-15 wt % arginine, and 1-15 wt % ornithine, 1-15 wt % alanine, 1-15 wt % glycine, 1-15 wt % serine, 1-15 wt % threonine 1-15 wt % valine, and 25-75 wt % 3-phenylacetyl-amino-2,6-piperidinedione.

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29 (Currently Amended): A pharmaceutical composition for alleviating or reducing ~~the toxic, nutritional and metabolic disturbances~~ fatigue and weakness associated with cancer and cancer chemotherapy consisting of: an effective amount of riboflavin; an effector of the urea cycle consisting of ~~comprising~~ arginine ~~and~~ ornithine, and mixtures thereof; ~~and~~ the amino acids alanine, glycine, serine, threonine and valine[[],]; ~~and~~ a suitable solvent, diluent, excipient, or carrier; and ~~optionally~~ 3-phenylacetyl-amino-2,6-piperidinedione.

30 (Cancelled)

31 (Original): The pharmaceutical composition of claim 29, consisting of 0.01-10 % riboflavin, 1-15 % arginine, and 1-15 wt % ornithine, 1-15 wt % alanine, 1-15 wt % glycine, 1-15 wt % serine, 1-15 wt % threonine 1-15 wt % valine, and 25-75 wt % 3-phenylacetyl-amino-2,6-piperidinedione.